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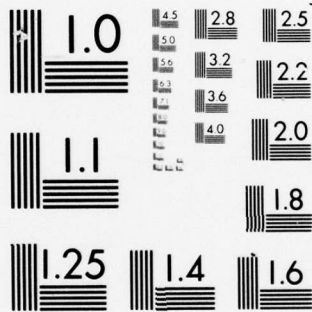
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REPORT NUMBER 8

SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

Annual Report

Craig R. Hassler and Larry G. McCoy

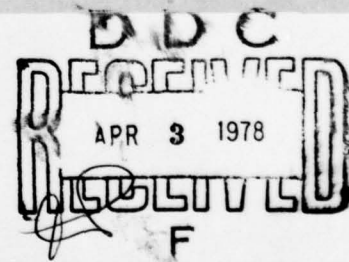
November 30, 1977

Supported by

U. S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Washington, D.C. 20314

Contract No. DADA17-69-C-9181

BATTELLE
Columbus Laboratories
505 King Avenue
Columbus, Ohio 43201



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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Long term implant studies involving high density alumina (Al ₂ O ₃) tooth roots have been undertaken in baboons using single root elliptical and rectangular design with serrations designed for maximal stress distribution. The roots are produced by cutting on a computer controlled milling machine. This technique allows for sizes and shape flexibility, and stress distribution area maximization. Both fresh extraction sites and edentulous sites have been used. The success rate for roots once they are ingrown and in function is approximately 90 percent. Most failures occur during this initial 2 to 3 month in-		

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→ growth period. This initial period has been found to be the most crucial period for implant "success." Previously the loss was approximately 40 percent during the ingrowth period in baboons. However, during this project year, the failure rate has been significantly reduced to approximately a 5% loss rate. ← Improved technique and minor design changes appear responsible for the improvement in "success" rate. The previously used elliptical tooth roots as well as rectangular roots are being evaluated. Implants are tapped into formed cavities in the alveolar bone. Once firmly stabilized by bone ingrowth, a prefabricated post and core is cemented into place and impressions taken. Gold crowns are fabricated to put the roots into function. Implants have remained rigid and in function for over two years. Histologic examinations show dense ingrowth of bone into serrations with little or no intervening connective tissue.

It is intended that the colony of baboons will be observed for several more years to truly evaluate the long term effects of these implants upon the health and function of the animal.

FOREWORD

This study has been conducted at Battelle's Columbus Laboratories utilizing the staff and resources of the Bioengineering/Health Sciences Section and the Ceramics Section. This is the Eighth Annual Report on progress under Contract No. DADA17-69-C-9181, "Surgical Tooth Implants, Combat and Field". The Principal Investigator for this research was Dr. Craig R. Hassler. He was ably assisted by Mr. Larry G. McCoy,

We are gratefully indebted to our dental consultants from The Ohio State University, College of Dentistry: Dr. Robert H. Downes and Dr. Orville E. Russell. The individual talents of these gentlemen in their respective fields of expertise has allowed this project to proceed successfully during the current project year.

We would additionally like to acknowledge the efforts of Mr. Lynn C. Clark for the histologic preparations used in this report.

In conducting the research described in this report, the investigators have adhered to the "Guide for Laboratory Animals Facilities and Care: as promulgated by the Committee on the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

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ABSTRACT

Long term implant studies involving high density alumina (Al_2O_3) tooth roots have been undertaken in baboons using single root elliptical and rectangular design with serrations designed for maximal stress distribution. The roots are produced by cutting on a computer controlled milling machine. This technique allows for sizes and shape flexibility, and stress distribution area maximization.

Both fresh extraction sites and edentulous sites have been used. The "success" rate for roots once they are ingrown and in function is approximately 90 percent. Most failures occur during this initial 2 to 3 month ingrowth period. This initial period has been found to be the most crucial period for implant "success". Previously the loss was approximately 40 percent during the ingrowth period in baboons. However during this project year, the failure rate has been significantly reduced to approximately a 5% loss rate. Improved technique and minor design changes appear responsible for the improvement in "success" rate. The previously used elliptical tooth roots as well as rectangular roots are being evaluated. Implants are tapped into formed cavities in the alveolar bone. Once firmly stabilized by bone ingrowth, a prefabricated post and core is cemented into place and impressions taken. Gold crowns are fabricated to put the roots into function. Implants have remained rigid and in function for over two years. Histologic examinations show dense ingrowth of bone into serrations with little or no intervening connective tissue.

It is intended that the colony of baboons will be observed for several more years to truly evaluate the long term effects of these implants upon the health and function of the animal.

TABLE OF CONTENTS

	<u>Page</u>
BACKGROUND	1
MATERIALS AND METHODS	2
Alumina Root Structures	2
IMPLANT STUDIES	8
Implantation	8
Restoration	8
Histologic Preparations	8
CONCLUSIONS AND RECOMMENDATIONS	22
REFERENCES	23

LIST OF FIGURES

Figure 1. Alumina Tooth Root as Produced for Baboon Implants in 1977	4
Figure 2. Steps in Grinding Technique. From Left to Right: Preground Bisque Fired Blank, Diamond Cutting Tool, Exterior Cut Root: Root Mounted for Interior Grinding and Tools for Interior Grinding	5
Figure 3. Comparison of Rectangular and Elliptical Tooth Roots Top View, The Recess and Tapered Pin Hole Can be Seen in Both Root Styles	7
Figure 4. Alumina Root with Prefabricated Post and Core in Position	9
Figure 5. Cross Section of Alumina Root in Function for 15 Months	12
Figure 6. Microscopic View of Serration Bone Interface at Tip of Serration	13
Figure 7. Bone Ceramic Interface	15
Figure 8. Microscopic Detail of Uppermost (First) Serration Showing Connective Tissue Above and Bone Below the Serration	16

LIST OF FIGURES
(Continued)

	<u>Page</u>
Figure 9. Radiograph of Alumina Implants Shortly After Placement. First Molar and Second Pre-molar Mandibular	17
Figure 10. Radiograph of Implants Following Reconstruction . . .	18
Figure 11. Implants 1 Month Post Reconstruction	19
Figure 12. Implants in Function for 2 Years.	20
Figure 13. Radiograph of Tooth Implants in Function for 2 Years .	21

SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

by

Craig R. Hassler and Larry G. McCoy

BACKGROUND

Research interest in dental restorations has continued to be a subject of intense research interest. Of particular interest in this project are implants which are designed to replace individual teeth. As noted in previous reports on this project,^{(1-9)*} a group of materials including porous titaniums,^(10,13,16) vitreous carbons,^(11,12) and ceramics^(9,14,15) remain of serious interest. Additionally, several different design philosophies are evident. They include: solid rod and shafts,⁽¹⁴⁾ screw devices,⁽¹⁵⁾ porous titanium^(10,13,16) devices of both uniform and non-uniform porosities^(10,16) and serrated designs of different types.^(9,11) The device which will be discussed in this report is serrated with the serrations arranged in such a manner that the maximal surface area is available for distribution and minimizing stresses placed upon the adjacent bone.

In recent years, materials mentioned above have remained in contention for prosthetic tooth roots as well as for use in other body replacement areas because of their previously observed biocompatibility even though more successful materials may be evolved in the future. Consequently, the materials persist because of their biocompatibility. Consequently, the greater problem with today's implants appears biomechanical in nature. Most difficulties arise because a complex structure such as the tooth is being replaced with a foreign non-viable structure. Attachment between the artificial material and the natural alveolar bone is of great concern. At present two different attachment modalities are mentioned by researchers. Design configurations such as porous pins and studs are serrated devices to provide an implant which attempts to form a rigid fixation. On the other hand, some

*References begin on page 23.

researchers have indicated the necessity for a pseudoperidontal ligament to be regenerated between the tooth root structure and bone. The tooth root design described in this report most closely resembles a rigid fixation. This design and similar designs by other researchers are successful because mastication forces applied upon the tooth root are distributed in such a manner that the stress placed upon alveolar bone is minimized. This is the fundamental concept upon which the tooth root described in this report is based.

MATERIALS AND METHODS

Alumina Root Structures

High-density, high-purity alumina root structures having a tapered serrated surface and incorporating a recessed top and hollow core were prepared for in vivo evaluation in baboons. The objective of these evaluations was to verify further the efficacy of the design and to provide additional histologic data on long-term functional implants. The design has continued to evolve. However, changes implemented during this project year were minimal.

Root Structure Design

During the 1974 and 1975 programs a new root structure design was developed which incorporated a hollow core and concentric elliptical recess to facilitate restoration. In vivo studies conducted with implants incorporating this termination concept have been highly successful.

In 1976 further improvements were made in the termination details to further facilitate restoration as well as to provide improved fabricability and structural integrity. The previous square core was modified to a conical core to facilitate casting of the gold post and core and to eliminate the corner stress-risers in the finished ceramic. The dimensions and details of the serrated root section of the implant were also modified. To provide a closer dimensional match to the natural dentition of the baboon, the cross sectional shape of the implant was made more elliptical and the length of the serrated section was increased. To maximize the horizontal area

available to support occlusal loads, the depth of the serrations was also increased by 50 percent (1 to 1.5 mm). Basic research on other projects in this laboratory indicates that it is desirable to maintain stress concentrations below 350 psi static load in bone to prevent resorption phenomena. The root structures modifications described above provide in all cases, except the 7 and 8 mm sizes, stresses below this level assuming a 160 pound static-axial occlusal load.

In 1977 the design of elliptical roots was unchanged except for elimination of the distinct finish line. This change made the surgical placement depth less critical. Additionally, rectangular implants were devised in an attempt to minimize the short term loss of implants especially noted in fresh extraction sites. A rectangular shape appears to give a better short term fit to the bone remaining following extraction.

Materials Selection and Fabrication Procedures

A process of contour grinding the root structure shape from dry-pressed or bisque-fired material developed and reported upon in our 7th annual report was used. A computer controlled milling machine was utilized. To generate the elliptical shape, an indexed rotary table was used to support the blank rod stock and the depth of the grinding head was varied as a function of the angular rotation of the piece, (i.e., the computer program for an ellipse was written in terms of $R = f(\theta)$). A change in the size or shape of the ellipse (i.e., the implant) requires only a change in the maximum and minimum R values of the program. The X and Y translation of the milling machine was used to produce the rectangular implants.

To generate the complete external contour of the root structure shown in Figure 1; a full length, diamond-plated contour grinding tool was designed and fabricated. The tool has the negative contour of the root structure and is designed to produce an as-ground shape that is approximately 13 percent oversize in all dimensions to allow for firing shrinkage. This tool is essentially identical to that produced for the previous year's implants.

The steps in the grinding operation are shown in Figure 2. The blank is preground using conventional equipment to remove excess material

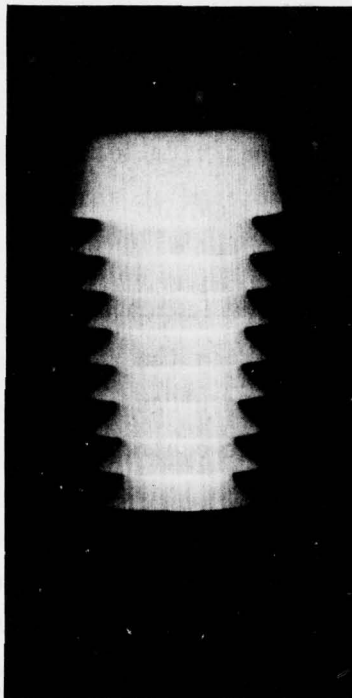


FIGURE 1. ALUMINA TOOTH ROOT AS PRODUCED
FOR BABOON IMPLANTS IN 1977

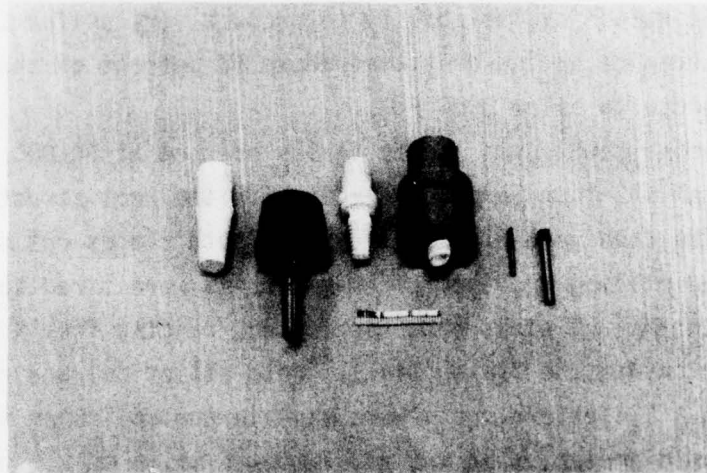


FIGURE 2. STEPS IN GRINDING TECHNIQUE. FROM LEFT TO RIGHT:
PREGROUND BISQUE FIRED BLANK, DIAMOND CUTTING
TOOL, EXTERIOR CUT ROOT: ROOT MOUNTED FOR
INTERIOR GRINDING AND TOOLS FOR INTERIOR
GRINDING

and to provide a smooth gripping surface. The elliptical or square contour is then ground on the computer-controlled machine. The root structure is ground in the inverted position to provide maximum support. The root is cut away from the stump and is then mounted in a matching plastic holder for grinding the recess and drilling the post hole. The holding fixtures for implants were improved to facilitate these operations.

The experimental implants were fabricated from a high-purity, extremely fine, thermally reactive grade (A-16 SG)* of alumina powder. This material is noted for its ability to produce very uniform, fine-grained, high-strength ceramics having densities above 98 percent of theoretical at sintering temperatures below 3000 F.

The alumina powder was isostatically pressed at 50,000 psi to form 1/2-inch diameter x 2-inch long rods from which the root structure shapes were ground. The rods were bisque fired and tooth shapes cut on the computer controlled milling machine. Then the roots were fired to full density.

Fourteen implant sizes were fabricated, ranging from 7 mm to 11 mm (maximum dimensions at the finish line). Both elliptical and rectangular roots were made. Elliptical roots were made in the following sizes; (major diameter x minor diameter) 7 mm x 5 mm, 7 mm x 6 mm, 8 mm x 6 mm, 9 mm x 7 mm, 10 mm x 8 mm, 11 mm x 9 mm. Rectangular roots were made in the following sizes; 7 mm x 6 mm, 8 mm x 6 mm, 9 mm x 6 mm, 9 mm x 7 mm, 10 mm x 7 mm, 10 mm x 8 mm, 11 mm x 8 mm, 11 mm x 9 mm. Twelve millimeteres of serrations were cut on all roots. A 3.5 mm non-serrated area was left at the top. Approximately 100 implants were prepared. Figure 3 presents a comparison of the cross section appearance between rectangular and elliptical implants. Since the most crucial period for implant success is the initial ingrowth period, the flexibility of selecting the best possible fit should enhance the probability of implant success. These precautions may not be necessary in a human subject where better cooperation can be anticipated.

*Alcoa A-16 Super Ground, Alumina Company of America, East St. Louis, Illinois.

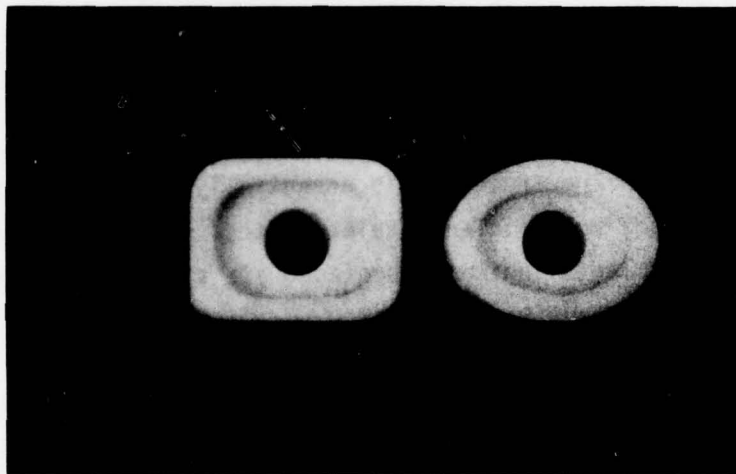


FIGURE 3. COMPARISON OF RECTANGULAR AND ELLIPTICAL TOOTH ROOTS, TOP VIEW, THE RECESS AND TAPERED PIN HOLE CAN BE SEEN IN BOTH ROOT STYLES

IMPLANT STUDIES

Implantation

Implant procedures have been performed in adult female baboons. Following an extraction, the mandibular tooth socket, either molar or premolar, is enlarged and deepened using a tapered bone burr. A fitting procedure is used in which the socket being formed is continually examined for fit using the implant. The root is then firmly tapped into place. The root is sunk until the first serration is in contact with the alveolar bone. The roots are given no further attention with the exception of administering a prophylactic antibiotic immediately postsurgery and a soft diet. The roots are then observed monthly for three months after which time reconstruction can usually be performed. The procedure is essentially similar for rectangular roots and placement of roots in endentulous sites. Both manual palpation and X-rays of the implants indicate when adequate stability through ingrowth of bone into the serrations has occurred.

Restoration

Prior to implantation of a ceramic tooth root, a gold post and core is fabricated for each root. The roots and accompanying post and core are then coded for eventual remating following implantation. This prefabrication eliminates the difficulty of taking impressions from a deeply seated implants in the oral cavity (Figure 4).

When ingrowth into the ceramic tooth root is judged to be adequate, the prefabricated post and core is cemented into position. An impression of the mouth including the post and core is then taken. A conventional gold crown is then fabricated, and cemented into place shortly thereafter. Care is taken to provide correct occlusion. The restored implant is then followed on a monthly basis. The implant is palpated for rigidity and documented by radiographs and photographs.

Histologic Preparations

Following necropsy, the area of alveolar bone including the implant is cut from the mandible of the animal and prepared for ground

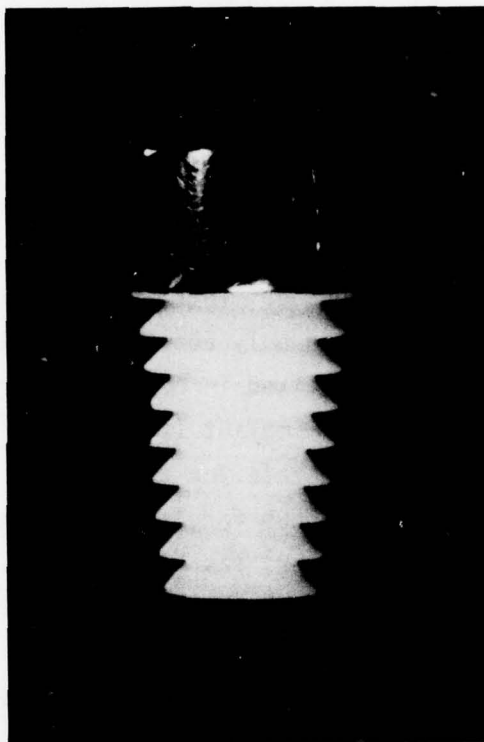


FIGURE 4. ALUMINA ROOT WITH PREFABRICATED
POST AND CORE IN POSITION

sectioning techniques. Initially the implant area is fixed in 70 percent ethyl alcohol or 10% neutral buffered formalin. The material is then subsequently stained with basic fuchsin and imbedded in methyl methacrylate for ground sections. Thin sections are prepared by decalcification, root removal, paraffin embedding and H&E stain.

Results

During this reporting period, an additional 24 roots have been implanted. These roots are presently in all stages of reconstruction. Gold reconstructions have been placed on 8 of these roots. One root has been lost and the remainder are still awaiting reconstruction. The most significant fact from this years' implants is that only one root has been lost during the initial 3 month ingrowth period. This is a remarkable change from the past history of the project where only 60% of the roots survived the initial three months and became rigidly fixed in bone structure. Since our failure rate has been low (10%) once the implant is rigidly fixed in place, we anticipate a lower total failure rate for this year. Six of these new roots are of the rectangular design. Thus far, little difference between the two designs (elliptical vs. rectangular) has been noticed. The only failure was an elliptical root. Subjectively a better initial fit to the socket was achieved using the rectangular roots.

In recent project history 20 ceramic roots have been restored to function. The longest period of functional "success" followed to date has been 25 months. the history of these "successful" roots has been as follows:

3 roots minimum of 24 months in function

4 " " " 12 " " "

2 " " " 9 " " "

3 " " " 6 " " "

7 " " " 1 month " "

1 failure at 1 month in function

20 Total

Of these roots, 13 are still in animals living in the colony of 9 baboons. The other roots were in baboons necropsied for histology.

In the past 2-1/2 years of implants, 84 roots have been followed. An overall failure rate of 37% has been noted. Virtually all of these failures were in the first three months post implant. These failures were either loss or loosening. Failure was slightly higher in fresh sites as compared to edentulous sites. As stated previously, the failure rate has been drastically reduced during the 1977 project year. There are three factors which may account for this failure reduction: (1) a greater selection of root sizes was available to assure better initial fit, (2) serration length of 12 mm was used. Previously 3 mm (2 serrations) was cut from the bottom of the root, (3) the top of the root was modified to make vertical placement less critical and give greater flexibility to the operating dentist.

The roots in function are judged "successful" by the following criteria:

- (1) Radiographic appearance of dense bone ingrowth into serrations.
- (2) Resistance to movement by manual palpation (rigid).
- (3) Minimal gingival irritation.
- (4) Maintenance of occlusion.

Roots which have remained rigid in the mouth are termed "potentially successful" until they are reconstructed. All "successful" roots listed in this study were implanted a minimum of 3 months before reconstruction. Our one failure with a reconstructed root has been where less than 3 months of ingrowth time was allowed. Failure was presumably due to lack of adequate stabilization.

Histologic Results

Figure 5 shows a low magnification view of a tooth implant in function for 15 months. The close proximity of bone to the lower serrations is typical of these implants. The curling of soft tissue into the upper most serration is also typical. The thin layering of bone beneath the implant is common. This cross section is typical of older style implants produced in 1975. Roots presently being produced are longer and have deeper serrations.

Figure 6 illustrates the very close approximation seen between bone and ceramic at the interface. This particular view is a cross section through the tip of a serration. This particular implant was in function for 21

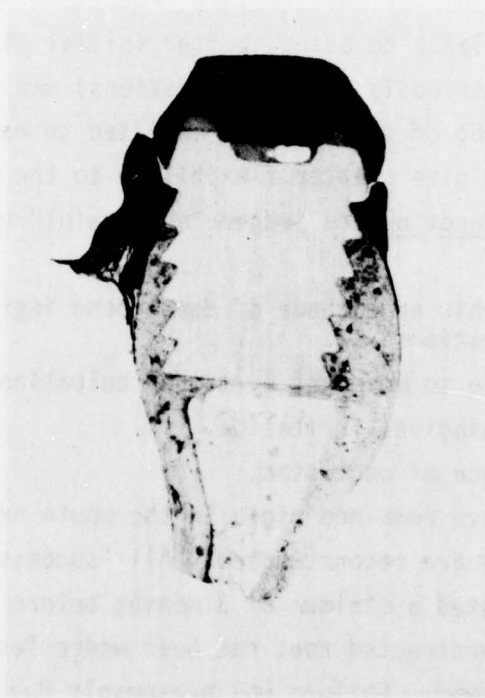


FIGURE 5. CROSS SECTION OF ALUMINA ROOT IN
FUNCTION FOR 15 MONTHS



50X

FIGURE 6. MICROSCOPIC VIEW OF SERRATION BONE
INTERFACE AT TIP OF SERRATION

months at the time of necropsy. Further examination of other sections reveal occasional small pockets of connective tissue in contact with the ceramic. Figure 7 illustrates a similar view of the interface at a higher magnification. This view emphasizes the intimate apposition between bone and ceramic often seen.

Figure 8 shows detail of the junction between connective tissue, ceramic and bone at the level of the first serration. As is often seen the connective tissue comes down to and/or wraps around the first serration. This particular specimen was in function for 21 months.

Radiographic and Photographic Results

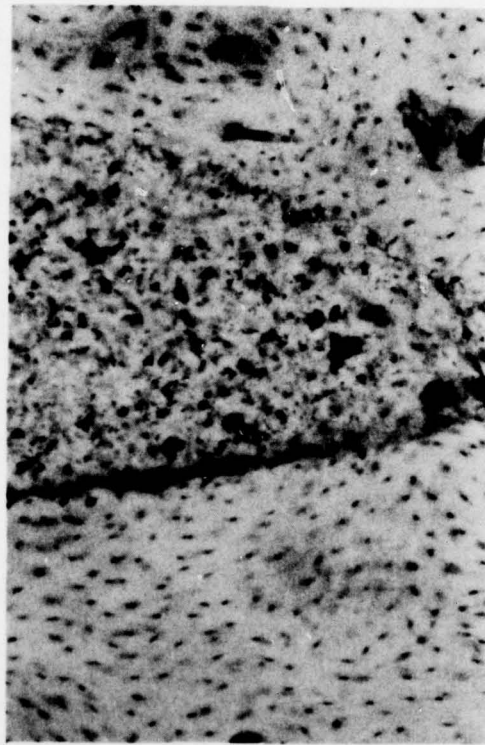
Figure 9 illustrates a radiographic view of implants shortly after their placement. Note that the lack of bone in serrations is readily apparent at this early stage. These implants are of the most recent style and length. Figure 10 shows these implants at the time of reconstruction. Post and cores are cemented into place, impressions taken and crowns cemented. Note that formation of bone is apparent in the serrations.

Figure 11 is a photograph of these implants 1 month after reconstruction. The gingival appearance of this implant is typical.

Figure 12 shows 2 implants which have been in function for 2 years. The gingival cuff has proliferated around some of the older implants. These older implants are in older animals with reduced vertical height. Older implants appear more resistant to bleeding when probed than newer implants. There is no gingival attachment to the prosthesis. Figure 13 is a radiograph of the same implants showing what appears to be extremely dense bone formation about the serrations. The serration detail appears to be masked due to the bone density. Loss of radiographic serration detail is typical of long term implants. Bone height about the implant has remained constant. This implant is still rigid and in occlusion.

Blood Chemistry, Hematology and Pathology

To assess the health of the baboons and any unusual effects of implants, a rather complete clinical chemistry and hematology profile has been compared to control. No animal has shown significant alteration of values from control. The only exception was a baboon necropsied this fall which was found lethargic. Blood chemistry indicated a profound hypoglycemia. Gross pathology indicated no pathology. It is unlikely that there is a



100X

FIGURE 7. BONE CERAMIC INTERFACE



50X

FIGURE 8. MICROSCOPIC DETAIL OF UPPERMOST (FIRST)
SERRATION SHOWING CONNECTIVE TISSUE
ABOVE AND BONE BELOW THE SERRATION

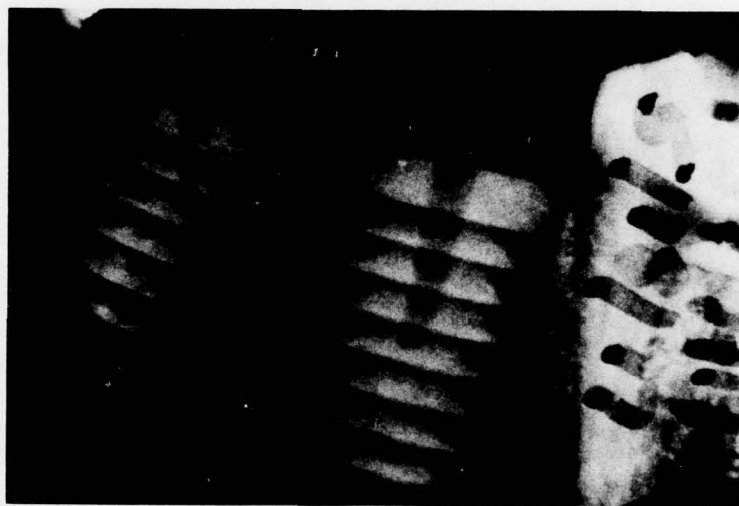


FIGURE 9. RADIOGRAPH OF ALUMINA IMPLANTS SHORTLY AFTER PLACEMENT. FIRST MOLAR AND SECOND PRE-MOLAR MANDIBULAR

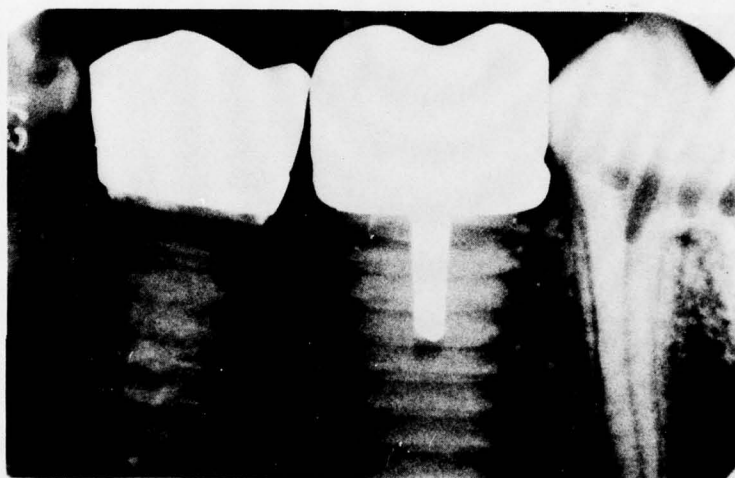


FIGURE 10. RADIOGRAPH OF IMPLANTS FOLLOWING
RECONSTRUCTION

(Same Implants as Figure 9)

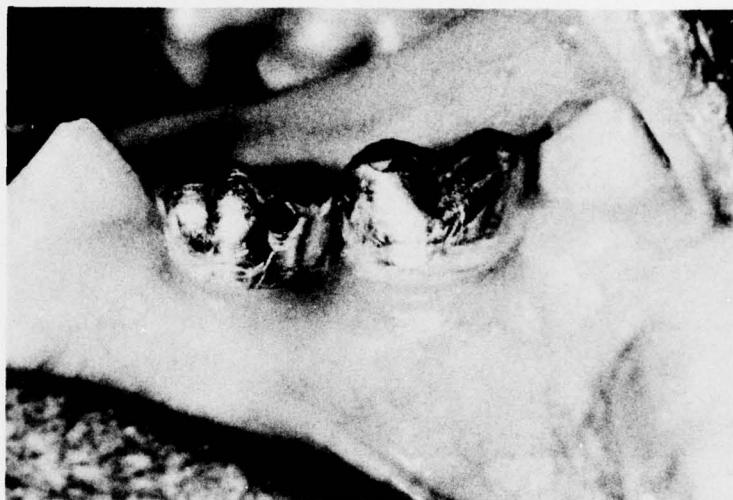


FIGURE 11. IMPLANTS 1 MONTH POST RECONSTRUCTION
(Same as Figures 9 and 10)



FIGURE 12. IMPLANTS IN FUNCTION FOR 2 YEARS

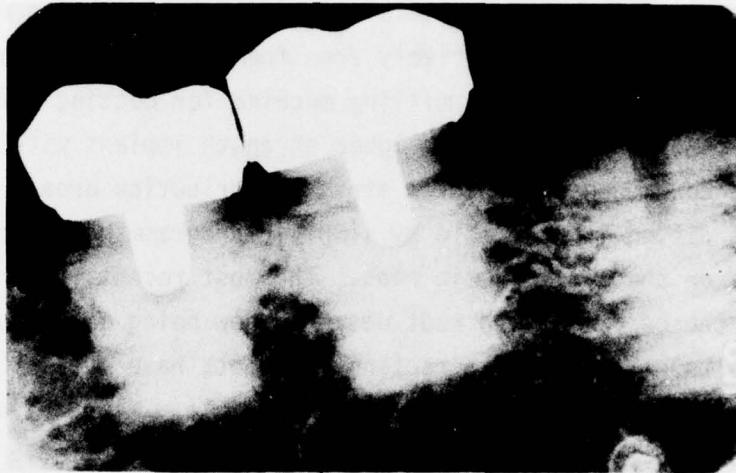


FIGURE 13. RADIOGRAPH OF TOOTH IMPLANTS IN
FUNCTION FOR 2 YEARS

connection between the implants in this animal and the profound hypoglycemia found. In all other animals necropsied for this project, no pathology has been noted.

CONCLUSIONS AND RECOMMENDATIONS

The research progress indicates that the ceramic serrated tooth root can be placed in full biomechanical function to provide a tooth replacement with a high probability of success. However, "success" is dependant upon completion of an initial ingrowth period during which the serrated tooth root must be relatively free from biomechanical stresses. The use of a computer controlled milling machine for cutting the alumina roots has provided a high quality, higher strength implant with deeper serrations and consequently improved stress distribution area. Additionally, flexibility of design is available by simply reprogramming the computer to change size or shape of ceramic root. The most recent implant studies indicate that the ceramic tooth root designed now being employed provides excellent results. Studies with rectangular roots have shown that a high initial "success" rate (ingrowth phase) is possible. However, due to the vastly improved "success" of elliptical roots this year, little difference in "potential success" rate between these two shapes was seen. Long term "success" of the two shapes will determine if both should be continued. There is some advantage in having a greater range of sizes and shapes to fit various implant sites properly. However, long term success must not be prejudiced for such an advantage.

It appears that an initial clinical investigation of these implants should be undertaken. A small population of patients involving using roots similar to those now being used in the baboon should be studied.

Simultaneously, the long term animal implants now underway should be observed for as long as practical. The oldest of these implants are now over two years in function and still appear "successful" according to our definitions. These animals will eventually provide valuable histologic data as to the fate of these implants. Additional sites are available

in these animals if pre-clinical experience in more difficult implant sites (i.e., 2 and 3rd molar mandibular and pre-molar maxillary) is desired.

The present method of root production is satisfactory for research purposes. Of major concern is the quality of individual roots being produced. An adequate quality assurance following accepted standards should be instituted to assure that the best possible implant is being produced for clinical studies. An advanced mathematical model of the serrated roots system would be a valuable asset to verify our assumptions and basic calculations as to manner of stress distribution by the implant design on the surrounding bone.

Studies to provide a practical gingival attachment should be reconsidered. Even though these roots appear to remain free from inflammation without an attachment to the prosthesis, such an attachment appears to be a desirable goal.

REFERENCES

- (1) Driskell, T.D., O'Hara, M.J., and Greene, G.W., Jr., D.D.S., "Surgical Tooth Implants, Combat and Field", Report No. 1, Contract No. DADA17-69-C-9181 (July, 1971).
- (2) Driskell, T.D., O'Hara, M.J., and Niesz, D.E., "Surgical Tooth Implants, Combat and Field", Report No. 2, Contract No. DADA17-69-C-9181 (April, 1973).
- (3) Driskell, T.D., McCoy, L.G., Tennery, V.J., and Niesz, D.E., "Surgical Tooth Implants, Combat and Field", Report No. 3, Contract No. DADA17-69-C-9181 (November, 1973).
- (4) Hassler, C.R., Driskell, T.D., McCoy, L.G., and Niesz, D.E., "Surgical Tooth Implants, Combat and Field", Report No. 4, Contract No. DADA17-69-C-9181 (February, 1974).
- (5) Hassler, C.R., and McCoy, L.G., "Surgical Tooth Implants, Combat and Field", Report No. 5, Contract No. DADA17-69-C-9181 (October, 1974).
- (6) Hassler, C.R. and McCoy, L.G., "Surgical Tooth Implants, Combat and Field", Report No. 6, Contract No. DADA17-69-C-9181 (October, 1975).
- (7) Hassler, C. R., McCoy, L.G., Downes, R.H., Racey, G.L., and Russell, O.E., Ceramic Tooth Implants in Primates, Jour. Dent. Res. 55B, 242, 1976.

- (8) Hassler, C. R., and McCoy, L.G., "Surgical Tooth Implants, Combat and Field", Report No. 7, Contract No. DADA17-69-C-9181 (October, 1976).
- (9) Hassler, C.R., McCoy, L.G., Downes, R., and Russell, R., "Ceramic Tooth Implants in Baboons:", Jour. Dent. Res. 56A, A117 (1977).
- (10) Rasmussen, J.J., Karagianes, M.T., Westerman, R.B., and Marshall, R.P., "Dental Anchors of Non-Natural Design Implanted in Miniature Swine", J. Dent. Res., 52, 124 (1973).
- (11) Mills, B.G., Chon, C.C., Voss, R., and Grenoble, D.B., "Effects of Vitreous Carbon Implants on Alveolar Bone Morphology", J. Dent. Res. 53, 129 (1974).
- (12) Lemons, J.E., Baswell, I.L., and T.E. Fisher, Laboratory and clinical studies of vitreous carbon tooth root replacement systems. Trans. 9th Intl. Biomaterials Symp. 1, 47 (1977).
- (13) Young, F.A., Funke, F. W., and Draughn, R.A., "New Concept in Dental Implants", Proc. 27th ACEMB, 16, 158 (1974).
- (14) Six year clinical experience with ceramics in Natural Tooth Form in Baboons. H. R. Stanley, L. Hench, J. Chellemi, R. Gainz, C. Bennett, J. Dent. Res. 55(B) 244, 1976.
- (15) Six year clinical experience with ceramic screw type dental anchors. Isaac Bar-oz, Proc. 2nd Ann. Soc. for Biomaterials, April, 1976.
- (16) Six year study of an Endosseous Dental Implant. M. B. Weiss, J. W. Rostoker and E. Ronen, J. Dent. Res. 55(B) 36, 1976.

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